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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/645,415	08/24/2000	David G. Bermudes	8002-059-999	3240

20583 7590 11/19/2002

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[REDACTED] EXAMINER

SHUKLA, RAM R

ART UNIT	PAPER NUMBER
1632	17

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/645,415	BERMUDES ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ram R. Shukla	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 28 August 2002.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 2-14, 16, 26-38, 40, 49-63, 72, 86, 94 and 100-141 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 2, 3-14, 16, 26-38, 40, 49-63, 72, 86, 94, 100-141 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ .                                   |

**DETAILED ACTION**

1. Response filed 8-22-02 has been received.
2. Amendment to claim 60 has been entered.
3. Claims 1, 15, 17-25, 39, 41-48, 62, 64-71, 85, 87-93 and 95-99 have been cancelled.
4. New claims 100-141 have been entered.
5. Claims 2, 3-14, 16, 26-38, 40, 49-63, 72, 86, 94, 100-141 are pending.
6. Applicant's election of the invention of group II (CLAIMS 2, 3-14, 16, 26-38, 40, 49-61, 63, 72-84, 86, and 94) in Paper No. 16 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicants further elected TNF -alpha as the species in TNF family, endostatin in anti-angiogenic factor, methionase in tumor inhibitory enzymes, verotoxin in the cytotoxic peptide family, ColE3 in bacteriocin family, dsDNA in the antisense molecule, ricin as the anti-tumor protein, cytosine deaminase in the pro-drug convertin enzyme, CEA in the immunomodulating agents and BRP in the release factor.
7. It is noted that upon further consideration and examination, it was determined that in addition to the above restriction/election, a further restriction/election is required as follows:
  - I. Claims 2, 3-14, 16, 26-38, 40, 49-61, 63 and 100-141, drawn to an attenuated tumor targeting bacteria, a pharmaceutical composition comprising the bacteria and a method of delivering an effector molecule to a tumor, classified in class 435, subclass 93.2.

II. Claims 72-86 and 94, drawn to a method of treating a tumor using a combination of a chemotherapeutic composition and an attenuated tumor targeting bacteria, classified in class 435, subclass 93.2.

8. Inventions of the groups I and II are patentably distinct. In the instant case, it is noted that while the bacteria of group I is used in the methods of the groups I and II, the methods are patentably distinct because the method group I can be practiced without the chemotherapeutic agent used in group II. Additionally, the chemotherapeutic agent of group II can be used independently of the bacteria of group I or in combination of other therapeutic agent. Therefore, the inventions of the groups I and II are patentably distinct.

9. This application contains claims directed to the following patentably distinct species of the claimed invention:

- Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, primary effector molecule is a genus that comprises the species of: TNF -alpha, anti-angiogenic factor, tumor inhibitory enzymes, cytotoxic peptides, bacteriocin family, hemolysin, CNF-1, CNF-2, and PMT.
- Regarding claim 12, applicants are required between- an animal, a plant, a bacterium and a virus.
- Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, secondary effector molecule is a genus that comprises the species of: an antisense molecule, a ribozyme, an antigen, an anti-tumor proteins, pro-drug converting enzyme, immunomodulating agents, bacteriocin release factor, an inhibitor of nitric

oxide synthase, an inhibitor of endothelial nitric oxide synthase and a release factor.

10. It is noted that while applicants have elected TNF -alpha as the species in TNF family, endostatin in anti-angiogenic factor, methionase in tumor inhibitory enzymes, verotoxin in the cytotoxic peptide family, ColE3 in bacteriocin family, dsDNA in the antisense molecule, ricin as the anti-tumor protein, cytosine deaminase in the pro-drug convertin enzyme, CEA in the immunomodulating agents and BRP in the release factor, they are advised to elect a species of the elected species, if the elected species of primary or secondary effector molecule is different from those already elected.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

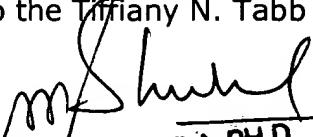
When amending claims, applicants are advised to submit a clean version of each amended claim (without underlining and bracketing) according to § 1.121(c). For instructions, Applicants are referred to

<http://www.uspto.gov/web/offices/dcom/olia/aipa/index.htm>.

Applicants are also requested to submit a copy of all the pending/under consideration claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for this Group is (703) 308-4242. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Tiffany N. Tabb whose telephone number is (703) 605-1238.

Ram R. Shukla, Ph.D.

  
RAM R. SHUKLA, PH.D.  
PATENT EXAMINER